REMARKS

Claims 1-11 are currently pending in the application. Claims 5 and 10-11 are amended. The amendments find support in the specification and are discussed below. No new matter is added. Individual bases for rejection are addressed below, and reconsideration of the rejections is requested.

APPLICANT'S INVENTION

Applicant's invention is directed to an agent delivery system and a method for delivering a therapeutic agent to tissue. The delivery system includes a pellet containing a therapeutic agent, and a flexible, implantable body with a hollow interior. The implantable body is implanted in the tissue to be treated with the agent, and the pellet is placed within it. The implantable body is configured to hold the pellet after implantation. The implantable body can be a helical spring, where the individual coils hold the pellet in place, and are spaced so as to allow bodily fluids to pass into the implantable body and come in contact with the pellet. The coils can be smaller at one or both of the ends, to keep the pellet within the implantable body.

The invention can also include an implant delivery device, and a tube for delivering the pellet, where the tube engages the proximal end of the implantable body. The delivery device can also include mechanisms for alignment of the device, restraint of the pellet, and advancement of the pellet(s). The alignment tool can be configured to fit within the inner diameter of the coils of the implantable body, or it can be configured to fit outside the outer diameter. The agent delivery system can also include a multi-lumen delivery tube, with a lumen for implant delivery and a lumen for pellet delivery. The two tubes can be independently controllable. The system can also include an obturator for piercing the tissue.

In use, the system can be used to deliver to tissue a therapeutic agent in the form of a pellet. For example, the obturator, loaded with the implant, is advanced into the tissue to deliver the implant. The tube for delivering the pellet is loaded with the pellet, inserted into the proximal end of the implantable body, and the pellet is pushed out of the tube and into the interior of the implantable body, within the space defined by the coils. The delivery tube is then removed, leaving behind the implantable body with the therapeutic pellet caged within. The

proximal end of the implantable body can be closed, *e.g.*, by crimping, so as to prevent escape of the pellet through the proximal end of the implantable body.

U.S. Pat. No. 3,443,561 (Reed *et al.*)

Reed *et al.* discloses an implant device in the form of two flat halves that fit together, with criss-crossed strips forming a porous upper and lower surface. Pellets of medicament are placed inside the device, and the medicament leaches out of the device through the top and bottom (through the criss-crossed strips). The device is not flexible.

U.S. Pat. No. 4,731,054 (Billeter *et al.*)

Billeter *et al.* discloses a device (a medical repository probe). It is a hollow tube, and is intended to be loaded with medicine carriers. The tube is made up along its length of separated segments and flexible joint zones. The tube has holes in it to allow the medicine to leach out of the medicine carriers and into the body of the patient. Billeter *et al.* does not disclose leaving the device within the patient's body, rather, it is clearly indicated that the device is intended to be removed at a later date. The reference also states that the tube can act as a drainage tube, that is, it is in fluid communication with the outside of the patient's body.

U.S. Pat. No. 5,062,829 (Pryor *et al.*)

Pryor *et al.* disclose a device to be implanted into the stomach of a cow, which releases a medicament. The deployed device is in the form of a segmented coil. The segments are joined together by connectors which also allow the undeployed device to be placed in a relatively flat position in a tubular applicator, which can be inserted into the animal. The device is then ejected into the animal via a plunger. Upon ejection, the coil "is resiliently biased into the expanded coil formation" (col. 3, lines 48-50).

The device is either made of a bioerodible material that includes the medicament, which is then released as the material erodes, or the device is made up of multiple hollow tubes that form a coil, with the medicament inside the tubes.

U.S. Pat. No. 5,984,890 (Gast *et al.*)

Gast *et al.* discloses a device for implanting solid or semi-solid implants or pellets under the skin. The device includes a tissue penetration guide for preventing the pellets or implants from being deposited too deeply. The guide is attached to the body of the device and is parallel to it, and is separated from the body of the device by a distance approximating the thickness of the tissue under which the pellets are to be deposited. Gast *et al.* states that the purpose of the device is to prevent medications intended for subcutaneous implantation from being delivered too deeply, and the reference does not include embodiments that do not include the depth guide.

Claim Amendments and Allowable Subject Matter

The Office Action states that there is insufficient antecedent basis for the term "implant device" in claim 10. Applicants respectfully submit that one of ordinary skill would understand the plain meaning of this claim, but have amended it nonetheless. Claim 11 has been amended to correct an obvious typographical error, which does not affect the scope or meaning of the claim in any way.

Claim 5 has also been amended to clarify the original scope of this claim, that the pellet is retained within the implantable body after it was been placed within the target tissue. This is supported throughout the specification and claims as originally filed, *e.g.*, at page 3, line 25; page 5, lines 5-7, etc.

The Office Action requests that applicants review the claims for minor antecedent basis problems. Applicants respectfully submit that the claims are clear on their face, and their meaning and scope would be readily understood by one of ordinary skill in the art. The requirement that the claims "particularly point out and distinctly claim" the invention is met when a person experienced in the field of the invention would understand the scope of the subject matter that is patented when the claim is read in conjunction with the rest of the specification. "If the claims when read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more." *Miles Laboratories, Inc. v. Shandon*, 997 F.2d 870, 875, 27 U.S.P.Q.2d 1123, 1126 (Fed. Cir. 1993); *see also Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692, 57 U.S.P.Q.2d 1293,

1297 (Fed. Cir. 2001); *North American Vaccine, Inc. v. American Cyanamid Co.*, F.3d 1571, 1579, 28 U.S.P.Q.2d 1333, 1339 (Fed. Cir. 1993); *Hybritech, Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1385, 231 U.S.P.Q. 81, 94-95 (Fed. Cir. 1986).

Nevertheless, Applicants would be amenable to re-phrasing some claim terms should the Examiner object to their current phrasing.

Claim Rejections Under 35 U.S.C. § 102

Claim 1 was rejected as anticipated by Reed *et al.* However, this reference does not disclose that the implant is flexible, as is required by claim 1. It therefore cannot anticipate applicants' invention, and the rejection should be withdrawn.

Claim 5 was rejected as anticipated by Billeter *et al.* Billeter *et al.* does not disclose that the device is left in the patient's body beyond the treatment period. For instance, column 2, lines 25-28 state that the joint zones could be formed as bellows to increase flexibility, but that this would interfere with painless removal of the probe. Column 5, lines 13-18 also discuss removal of the probe from the patient. The dual purpose of the probe as a medicine delivery device and a drainage tube is also discussed throughout this reference, for instance, at column 2, lines 35-66, column 4, lines 16-21 and 33-42, and at column 6, lines 10-12 and 44-46. Furthermore, column 1, lines 41-45 discuss the desired properties of the probe, including that it be as flexible as possible so that the probe can be pushed with greater ease into "anatomically provided" passages or canals, that is, pre-existing orifices.

In contrast, the claimed agent delivery system recites that the implantable body retains the pellet after the body has been implanted within the tissue, that is, the claimed delivery system leaves the implant within the patient's body. Claim 5 has been amended to a form similar to claim 1, which states that the implantable body is implanted "within" tissue. This is neither taught nor suggested by Billeter *et al.*, and this reference therefore cannot anticipate the claimed agent delivery system. Applicants therefore respectfully request that the rejection on this basis be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 2, 6-8 and 10 were rejected as unpatentable over Billeter *et al.*, Pryor *et al.* and Gast *et al.*

Claim 2 recites an agent delivery system which includes an implantable body in the form of a helical spring, where the individual coils of the spring define an inside diameter. It is within this inside diameter that the therapeutic pellet is placed and retained.

As noted in the Office Action, Billeter *et al.* does not disclose an implantable body in the form of a helical spring, nor does it disclose an obturator or insertion device. Pryor *et al.* discloses a coil-shaped device, which is either made of a bioerodible material containing a medicament, or is hollow and contains the medicament within the tube making up the coil. However, none of the references either teach or suggest, alone or in combination, the placement of the therapeutic pellet within the coils of a helical device, as is required by claim 2. This claim specifically states that the helical spring has individual coils which define an inside diameter suitable for retaining the pellet. The coils are also stated to be spaced at a distance which prevents passage of the pellet from the interior of the device. This is illustrated in Fig. 2.

The device of Pryor *et al.* releases medicine from inside the coiled hollow tube, not from within the void formed within the coils of the device. Furthermore, the device of Pryor *et al.* cannot be used as described in claim 2 -- if a pellet were to be placed within the coils of the Pryor *et al.* device and not escape, it would have to be so large that it would take up a large volume of the stomach. The combination of Billeter *et al.* and Pryor *et al.* are not combinable, they produce an inoperable embodiment if combined, and their combination represents a hindsight reconstruction of the claimed invention.

Gast *et al.* is cited for an obturator/insertion device for placing the pellets within the body, but this reference clearly states that its intention is to deliver pellets subcutaneously to a prescribed depth under the surface of the tissue. The figure cited in the Office Action (Fig. 2) shows the device being inserted through the skin. Fig. 3, however, shows the device "directed properly into a subcutaneous location." This reference therefore does not teach implantation other than at a subcutaneous location, or insertion of the device in a manner other than parallel to the skin.

Claims 6-8 depend from claim 5, which includes a pellet delivery tube which can be engaged with the proximal end of the implantable body. Claim 8 additionally discloses a pellet advancement mechanism and a pellet restraint mechanism. None of the cited references discusses a pellet delivery tube, or mechanisms for advancing or restraining the pellets. In addition, claim 6 states that the alignment tool can be engaged with the interior of the implantable body. Fig. 2 of Pryor *et al.* shows the opposite -- the delivery tube surrounds the disarticulated coil. The combined references therefore do not teach the claimed invention.

Claim 10 also includes an insertion device that holds the pellet inside the implantable body for simultaneous delivery of both the implantable body and the pellet. This is not shown in any of the cited references.

Combining the cited references does not teach the placement of a therapeutic pellet within the coil of a helical implantable body, as is required by claim 2, and none of the references teach or suggest the pellet delivery tube of claim 5, or an insertion device that holds both the implantable body and the pellet, so that both can be inserted simultaneously. Reconsideration of the rejection is therefore requested.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,

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Attorney Docket No. B0410/7278
Date: April 9, 2004